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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,064	04/20/2005	Scott Alan Jelinksy	AM100877	8561

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EXAMINER	
LUNDGREN, JEFFREY S	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,064	JELINKSY ET AL.	
	Examiner	Art Unit	
	Jeffrey S. Lundgren	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-59 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-59 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-9, are drawn to a plurality of genes differentially expressed in kidney cells comprising a first and second group of genes.

Group II, claims 9-14, are drawn to a method of using the plurality of genes in Group I.

Group III, claims 15-18, are drawn to an agent identified by the method of Group II, and pharmaceutical compositions thereof.

Group IV, claims 19, 22 and 23 (in-part), are drawn to a method for identifying an agent capable of maintaining vascular volume in septic shock.

Group V, claims 20, 22 and 23 (in-part), are drawn to a method for identifying an agent capable of enhancing calcium uptake in post-menopausal women.

Group VI, claims 21-23 (in-part), are drawn to a method for identifying an agent for treating cardiovascular disorders.

Group VII, claims 24 and 26, and claims 25 and 27 to the extent that they depend from claim 21, are drawn to an agent identified by the method of claim 21.

Group VIII, claims 25 and 27 to the extent that they depend from claim 19, are drawn to an agent identified by the method of claim 22.

Group IX, claims 25 and 27 to the extent that they depend from claim 20, are drawn to an agent identified by the method of claim 22.

Group X, claims 28-34, are drawn to a plurality of genes differentially expressed in pituitary cells, comprising a first group and second group of genes.

Group XI, claims 35-37, are drawn to a method for identifying a biological effect of estrogen in pituitary cells, comprising the use of a first plurality of genes and a second plurality of genes.

Group XII, claims 38-39, are drawn to an agent identified by the method of Group XI, and a pharmaceutical composition thereof.

Group XIII, claims 40-49, are drawn to a plurality of genes differentially expressed in uterus cells, comprising a first group and second group of genes.

Group XIV, claims 50-52, are drawn to a method for identifying a biological effect of estrogen in uterus cells, comprising the use of a first plurality of genes and a second plurality of genes.

Group XV, claims 53 and 54, are drawn to an agent identified by the method of Group XIII, and a pharmaceutical composition thereof.

Group XVI, claim 55, is drawn to a plurality of genes, wherein the expression levels of the genes are confirmed by real-time PCR.

Group XVII, claim 56, is drawn to a method of identifying claims [*sic*].

Group XVIII, claim 57, is drawn to a solid substrate comprising a plurality of genes.

Group XIX, claim 58, is drawn to the solid substrate of claim 55 [*sic*].

Group XX, claim 59, is drawn to a kit comprising a plurality of genes.

For the rules governing a lack of unity determination, see 37 CFR § 1.475 – *Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage* (especially paragraphs (a), (c) and (d)).

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or

(2) A product and process of use of said product; or

(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

The inventions listed as Groups I-XX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the a same or corresponding special technical features that defines a contribution over the art.

In the instant case, the technical feature linking the first product (*i.e.*, Group I) with the first method of using the product (*i.e.*, Group II), appears to be the plurality of genes differentially expressed in the kidney cells in response to hormones, wherein the plurality comprises a first group of genes and a second group of genes, the first group of genes is differentially expressed at higher levels than normal, the second group of genes is differentially expressed at lower levels than normal. However, this technical feature is taught by Melia *et al.*, *Endocrinology 139(2)*:688-695 (**1998**). Consequently, the technical feature that links Groups I and II does not constitute a "special" technical feature as required by PCT Rule 13.2, because it does not represent a contribution over the art.

Furthermore, Groups III-XX represent multiple products, processes of manufacture or uses that do not fall within the "main invention" as set forth in 37 CFR § 1.475(d). Group I is also not so linked with any of the Groups III-XX, for similar reasons, including but not limited to, the plurality of genes of Group I is either directed to chemically, functionally and structurally different compositions when compared to other composition groups, or is used in a materially different manner for a functionally different purposes of each method group, and therefore lack unity.

Furthermore, a search and examination of more than one invention as defined above would unduly burden the Office. Each of the inventions relates to different technical features, requires a different search of the art, and concerns separate considerations of patentability. For example, the subject matter of many of the inventions is not largely co-extensive, as the inventions are relate to different tissue types and involve a large number of chemically and functionally different genes. Therefore, restriction as define above is proper.

Species Election

This application contains claims directed to the following five (5) patentably distinct sets of species:

A. the "hormone effect" – Applicants must select a single combination of hormones/agents having the claimed biological effect, *e.g.*, estrogen, or the combination of estrogen and testosterone, etc. (the combination may be a single hormone/agent);

B. the "first group" – Applicants must elect a single combination of *specific* differentially expressed genes that is expressed at higher levels, *e.g.*, NTT73 and ABCC3;

C. the "second group" – Applicants must elect a single combination of *specific* differentially expressed genes that is expressed at lower levels, *e.g.*, BHMT and SAHH;

D. the "first plurality" – Applicants must elect a single combination of *specific* genes differentially expressed at various levels;

E. the "second plurality" – Applicants must elect a single combination of *specific* genes that are differentially expressed without exposure to a given agent;

PCT Rule 13.2 states that unity of invention shall be fulfilled when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(a) All alternatives have a common property or activity; ***and***

(b)(1) A common structure is present (*i.e.*, a significant structural element is shared by all of the alternatives); or

(B)(2) I n cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertain

Here, the claimed genes, hormones and/or agents, do not all have a common property or activity, and possess different structures. For example, different hormone have unique chemical structures that possess unique activities, such as the expression of various kidney tissue profiles (*i.e.*, testosterone *vs.* androstane). Additionally, many of the genes expressed in the plurality are structurally unique, such as each having a different nucleotide sequence not belonging to a common genus sequence, and act in unique ways, such as biological functions (*i.e.*, kidney androgen-regulated protein *vs.* organic anion transporter).

Accordingly, restriction to a single species as defined above is proper.

Applicants are advised that a reply to this requirement must include an identification of the species for each set that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. No matter which group Applicants elect, Applicants should identify which claims they believe are generic for each of the corresponding species sets A-E, and which claims read on a particular species within the species sets A-E. For example, Applicants' reply might state "...claim X is generic to the elected species of species sets A, C and E, but reads on the particular elected species for species sets B and D." Should a given species not pertain to Applicants' elected group, Applicants should indicate accordingly. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, Applicants will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR § 1.141. If claims are added after the election, Applicants must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should Applicants traverse on the ground that the species are not patentably distinct, Applicants should submit evidence or identify such evidence now of record showing the species

to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete, the reply must include an election of the invention to be examined even though the requirement be traversed (37 CFR § 1.43). This election includes an election of a single group, and an election of each species. Because the above restriction/election requirement is complex, a telephone call to Applicant to request an oral election was not made. See MPEP § 812.01.

Consideration of Rejoinder

The Examiner has required restriction between product and process claims. Where Applicants elect claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise **include all the limitations of the allowable product claim** will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR § 1.116; amendments submitted after allowance are governed by 37 CFR § 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR § 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§ 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy,

Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

Correction of Inventorship

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Time for Reply

Applicant is reminded that 1-month (not less than 30 days) shortened statutory period will be set for reply when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program.

Conclusions

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey S. Lundgren whose telephone number is 571-272-5541. The examiner can normally be reached on 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSL

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